

REMARKS

Claims 1–24 and 31–44 were pending in the application prior to the entry of this amendment. Applicants thank Examiner Mitchell for the interview with the Applicants' attorney Sabin Lee on July 7, 2004.

Elections/Restrictions

Claims 22–24, 31–34, and 41–44 are withdrawn from consideration without prejudice or disclaimer. Applicants reserve the right to pursue these claims and others in one or more continuation and/or divisional applications.

Claim Rejections Under 35 U.S.C. § 112

Applicants have made the following amendments solely to clarify the claims. The amendments are not intended to narrow or otherwise limit the scope of the claims in any way. None of these amendments constitutes new matter.

Claims 1–21, 36–40, and 42–44 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite.

Claims 2–21, 36–40, and 42–44 stand rejected for a lack of antecedent basis for reciting “the invention” in the preamble. The preambles of claims 2–21, 36–40, and 42–44 have been amended to recite “the apparatus.” Applicants respectfully submit that the rejection is overcome.

Claims 1–21 stand rejected as indefinite for reciting “a pressure representative of the appliance.” Claim 1 has been amended to delete the phrase and now recites “a pressure differential between a reference chamber pressure and an outlet port pressure.” Applicants respectfully submit that the rejection is overcome.

Claims 1–21 stand rejected as indefinite for reciting a demand valve comprising a plurality of valves. Claim 1 has been amended to recite “a demand valve assembly.” Applicants respectfully submit that the rejection is overcome.

Claim 4 stands rejected as indefinite for reciting “a second valve” without the recitation of a “first valve.” Claim 4 has been amended to recite “a control valve” rather than “a second valve.” Applicants respectfully submit that the rejection is overcome.

Claim 7 stands rejected for a lack of antecedent basis for reciting “the nebulizer outlet.” Claim 7 has been amended to depend on claim 5, which recites “a pressurized nebulizer outlet.” Applicants respectfully submit that the rejection is overcome.

Claim 7 stands rejected for a lack of antecedent basis for reciting “the third valve.” Claim 7 has been amended to recite “the nebulizer valve” and to depend on claim 5. Applicants respectfully submit that the rejection is overcome.

Claim 12 stands rejected for a lack of antecedent basis for reciting “the third valve.” Claim 12 has been amended to recite “a nebulizer valve.” Applicants respectfully submit that the rejection is overcome.

Claim 12 stands rejected for a lack of antecedent basis for reciting “the nebulizer outlet.” Claim 12 has been amended to recite “a nebulizer outlet.” Applicants respectfully submit that the rejection is overcome.

Claim 13 stands rejected for lack of antecedent basis for reciting “said at least one adjustable pressure regulator.” Claim 13 has been amended to delete the word “said.” Applicants respectfully submit that the rejection is overcome.

Claim Rejections Under 35 U.S.C. § 102

Claims 1–4, 6, 8–10, and 35–37 stand rejected under 35 U.S.C. § 102(b) as anticipated by Hatch (U.S. Patent No. 4,838,257). In order to anticipate a claim, a reference must disclose every element of the claim. Independent claims 1 and 35 have been amended to recite “a *pneumatically controlled*” continuous positive airway pressure (“CPAP”) apparatus. The apparatus disclosed in Hatch is *electromagnetically controlled*, as illustrated in FIG. 1. For example, the Abstract provides that “Each control valve is operated by a Venturi flow pilot valve having a variable exhaust flow which is a function of an electromagnetic linear actuator. Operation of the electromagnetic actuator is accurately controlled by computer hardware and software.” Parts 18, 20, and 54 in FIG. 1 are labeled “Pressure Monitor” and “Pressure and Flow Monitor.” Pilot valves 15 and 16 are shown controlled by a computer 17. The specification provides that “The monitors 18, 20 and 54 are operably connected to computer 17 in feedback loops that give the computer 17 the ability to vary operation of valves 15 and 16 to meet instantaneous needs of the patient.” Hatch at 6:29–33. Because Hatch does not disclose a pneumatically controlled apparatus, Hatch does not disclose or suggest every element of claims 1 and 35. Consequently, Applicants respectfully submit that Hatch does not anticipate or make obvious claims 1 and 35, and that the rejection is overcome. Claims 2–4, 6, 8–10, and 36–37 are dependent on claim 1 or claim 35 and recite additional patentable features that are neither anticipated by or obvious over

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the cited reference. Accordingly, Applicants respectfully submit that, for the same reasons as provided above, the rejection of these claims is also overcome.

Claim Rejections Under 35 U.S.C. § 103

Claims 11, 14, and 16 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Hatch. A rejection for obviousness must meet three criteria: (1) the cited reference or references must disclose or suggest every element of the claim; (2) a suggestion or motivation, in the references or known to one skilled in the art, to modify or combine the references; and (3) a reasonable expectation of success. The suggestion to combine and the reasonable expectation of success must be found in the prior art. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Claims 11, 14 and 16 are dependent on claim 1. As discussed above, Hatch does not disclose or suggest every element recited in claim 1, and consequently, does not anticipate or make obvious claim 1. Because claims 11, 14, and 16 are dependent on claim 1 and further recite additional patentable features that are not disclosed or suggested in Hatch, Hatch also does not disclose or suggest every element recited in claims 11, 14, and 16, and consequently, does not make obvious claims 11, 14, or 16. Consequently, Applicants respectfully submit that the rejection is overcome.

Claims 5, 7, 12, and 38 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Hatch in view of Davenport. Claims 5, 7, and 12 are dependent on claim 1. Claim 38 is dependent on claim 35. As discussed above, Hatch does not disclose or suggest a *pneumatically controlled* CPAP apparatus. Accordingly, if Hatch and Davenport in combination do not disclose or suggest the pneumatically controlled CPAP apparatus recited in claims 1 or 35, then claims 5, 7, 12, and 38 cannot be obvious over Hatch in view of Davenport.

Davenport discloses a pneumatically operated gas demand valve, which, as illustrated in FIG. 9, may be used with a nebulizer. Applicants respectfully submit that one skilled in the art would not be motivated to combine Hatch with Davenport, and even if he were so motivated, would not arrive at the subject-matter of claims 1 or 35.

First, Hatch teaches against pneumatically/mechanically controlled valves and, instead, favors computer control:

Finally, manufacturing technology requirements should, if possible, be reduced by relying more upon electronic means for the elaborate control processing such a

multi-function ventilator requires. Mechanical/pneumatic control devices should therefore be kept small in size, simple in operation, readily maintainable, and inexpensive to manufacture. Operation and stability should be primarily managed by means of computer controls. This increases functional capability of the system and reduces its manufacturing costs.

Hatch at 1: 48–57.

Consequently, one skilled in the art would not replace the computer control favored by Hatch with pneumatic control disclosed in Davenport.

Second, it is not clear how one would combine Hatch with Davenport to arrive at a pneumatically controlled apparatus. The Hatch apparatus is illustrated schematically in FIG. 1. The Davenport apparatus is illustrated in FIG. 4. Aside from a gas supply (Hatch 10, Davenport 14), a tube through which breathable gas is supplied to the user (Hatch 14, Davenport 20), and a tube through which exhaled gas returns to the apparatus (Hatch 13, Davenport 24), the two apparatus have little in common. It is unclear how one would combine the disclosures of Hatch and Davenport to arrive at the subject matter recited in claims 1 and 35 of the present application because Hatch is computer controlled, which Davenport discloses a pneumatic device. Consequently, Applicants respectfully submit that claims 1 and 35 are not obvious over Hatch in view of Davenport. Because claims 5, 7, 12, and 38 are dependent on claims 1 or 35, and because each of the dependent claims recites additional patentable features, Applicants respectfully submit that the rejection is overcome.

Claims 13, 15–17, 20, and 39 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Hatch in view of Foote. Claims 13, 15–17, and 20 are dependent on claim 1. Claim 39 is dependent of claim 35. As discussed above, Hatch does not disclose or suggest every element recited in independent claims 1 and 35, and in particular, pneumatic control. Applicants respectfully submit that the combination of Hatch and Foote also do not disclose or suggest every element recited in claims 1 and 35, and therefore, do not disclose or suggest every element recited in claims 13, 15–17, 20, and 39. Foote discloses a mixing valve for mixing air with oxygen, the mixture of which is provided as a source gas for a breathing demand regulator. Foote at 2:4–9. Foote does not disclose or suggest a pneumatically controlled breathing demand regulator. Consequently, the combination of Hatch and Foote do not disclose or suggest every element recited in claims 1 and 35, and by extension, do not disclose or suggest every element

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recited in claims 13, 15-17, 20, and 39. Accordingly, Applicants respectfully submit that the rejection is overcome.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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